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April 7, 2004

Docket No. 03-080-1
Regulatory Analysis and Development
PPD, APHIS, Station 3C71
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Sent Via E-Mail: regulations@aphis.usda.gov.

Re: Docket No. 03-080-1: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities – R-CALF USA’s Addendum to Comments Submitted on January 5, 2004

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Dear Administrator:

Thank you for the second opportunity to comment on the Animal Plant Health Inspection Service’s (APHIS’s) proposal to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and to add Canada to this category.

The Ranchers-Cattlemen Action Legal Fund - United Stockgrowers of America (R-CALF USA) is a non-profit association representing over 52,000 cattle producers, 8400 of which are voluntary, dues-paying R-CALF USA members and over 43,000 are members of R-CALF USA’s 58 affiliated cattle associations. R-CALF USA represents U.S. cattle producers on issues concerning national and international trade and marketing and is dedicated to ensuring the continued profitability and viability of the U.S. cattle industry. R-CALF USA’s membership consists primarily of cow-calf operators, cattle backgrounders, and independent feedlot owners along with local, state and regional cattle associations which represent same. Various main street businesses are associate members of R-CALF USA.

R-CALF USA had previously submitted comprehensive comments to APHIS on this subject on January 5, 2004. In its 18-page comment, R-CALF USA urged APHIS to withdraw its proposed rule based on the compelling body of science that indicates the United States’ cattle industry would assume both greater and unnecessary risk of introducing BSE into its herd and United State’s consumers would be subjected to both greater and unnecessary risk if the United States’ did not continue to enforce its longstanding policy of prohibiting the importation of ruminants and ruminant products from any country known to have BSE.

Because APHIS was not moved by R-CALF USA’s January 5, 2004, request to withdraw the proposed rule, the following comments will provide additional information demonstrating that the APHIS proposed rule is reckless and irresponsible, and constitutes an endangerment of the health and economic viability of the United States cattle industry.

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The APHIS proposal to amend its regulations to recognize a category of regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products, and to add Canada to this category should be withdrawn entirely for the following reasons:

1. Secretary Veneman’s Own Advisory Committee on Foreign Animal and Poultry Diseases Cautioned Her Against Making BSE-related Regulatory Decisions Until a More Thorough Scientific Risk Assessment is Completed.

The Secretary’s Advisory Committee on Foreign Animal and Poultry Diseases reported:

“ . . . [T]he Committee cannot adequately resolve the differing BSE risk assessment presented by the Subcommittee [International Review Subcommittee] compared to the assessment by Harvard University. . . The Committee must have this issue of risk resolved prior to completing its recommendations to the Secretary. It is imperative that the Secretary has the best available science and more precise risk assessments in order to make appropriate regulatory decisions.”¹

After establishing that there is a major discrepancy between the scientific risk assessments completed by the International Review Subcommittee and Harvard University, the Committee reiterated the need to reconcile the discrepancy before making any future decisions. In the report’s conclusion, the Committee wrote, “It is imperative that all future decisions be based on the best available science and that all necessary steps be taken to protect the safety of the public as well as the economic viability of animal agriculture in the United States.”²

R-CALF USA supports the Committee’s recommendation regarding the risk assessment and urges APHIS to withdraw its proposed rule until the United States completes a new risk assessment that definitively establishes the United States risk of exposure to BSE from countries known to have BSE in their cattle herd.

2. Not Only is there a Major Discrepancy Between the United State’s Own Risk Assessments, But Also, there is a Major Discrepancy Regarding the Prevalence of the BSE Agent in Canada.

The October 2003 update to the Harvard University Risk analysis directly contradicts the USDA’s in-house risk analysis also conducted in October 2003 which describes the prevalence of BSE in Canada as “low” based on “only a single infected Canadian animal that has been identified.”³ However, the independent Harvard University Analysis, which was also conducted before the second Canadian BSE case, contradicts the USDA claim by saying the prevalence of BSE in Canada could not be determined because of the “absence of strong evidence about the

¹ Report to the Secretary’s Advisory Committee on Foreign Animal and Poultry Disease, Measures Relating to Bovine Spongiform Encephalopathy in the United States, February 13, 2004, at 2.

² Id. at 3.

³ Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, USDA – Animal and Plant Health Inspection Service, Veterinary Services, October 2003, at 31.

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prevalence of BSE in the Canadian herd.”⁴ Notwithstanding the fact that even the APHIS claim that Canada’s BSE prevalence is “low” cannot be supported, cannot be verified, and contradicts the more exhaustive Harvard study, APHIS further misrepresented its own findings by subsequently downgrading Canada’s BSE prevalence to “very low” in its February 2004 Explanatory Notes and in the Federal Register notice of March 8, 2004, without any support or evidence.

R-CALF USA is concerned that the foregoing evidence suggests that APHIS is ignoring science, ignoring the actual risks, and is assuming a “lobbyist role” in its efforts to expose the U.S. cattle industry to greater risk.

3. APHIS’s Conclusion that the BSE Case in a Second Cow of Canadian Origin Does Not Alter Its Initial Risk Estimate is Without Foundation Because Neither APHIS Nor Canada has Taken, Nor do they Plan to Take, Any Meaningful Steps to Determine the Prevalence of BSE in Canada.

As stated previously, APHIS’s initial risk estimate described the prevalence of BSE in Canada as “low” based on “only a single infected Canadian animal that has been identified.”⁵ However, there have now been two cases of BSE originating from Canada, and in neither case has the source of the BSE infection been identified. APHIS acknowledges that the Canadian Food Safety Inspection Service is continuing its epidemiological investigation into the feed sources of the herd of origin.⁶ Until the source of the contaminated feed is known, it is not possible to definitively conclude the age of the index cows at the time of infectivity. Even though animals are more susceptible during the first six months of life, the two- to eight-year incubation period for BSE provides the possibility that both infected cows were infected after the Canadian feed ban was in place. Moreover, the second index cow was less than six months old when Canada’s feed ban was implemented.

The combined unknown source of infectivity and unknown timing of infectivity establishes a possibility that both index cows ingested the BSE agent after the feed ban was in place – a scenario suggesting there could be a continuing risk of BSE in younger Canadian cattle. APHIS must either identify the source and timing of infection in order to conclude that the prevalence of BSE is low in Canada, or Canada must begin testing a more representative sample of the Canadian herd than it is presently contemplating. Canada is planning to test approximately 8000 head of cattle during the next 12 months.⁷ Based on Canada’s 1999 herd size of nearly 13 million head, Canada plans to test less than .062 percent of its herd. While this level of surveillance may suffice for a country in which BSE is not known to exist, it is woefully

⁴ Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada, Joshua T. Cohen and George M. Gray, Harvard Center for Risk Analysis, Harvard School of Public Health, at 2.

⁵ Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, USDA – Animal and Plant Health Inspection Service, Veterinary Services, October 2003, at 31.

⁶ Explanatory Note: Risk Analysis: BSE Risk of Importation of Designated Ruminants and Ruminant Products from Canada into the United States, USDA Animal Plant Health Inspection Service, Veterinary Services, February 2004, at 7.

⁷ Id. at 7.

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inadequate for a country which produced two cases of BSE in less than 12 months under limited surveillance.

Lacking any definitive evidence regarding the exact source of infectivity and timing of infectivity, Canada should be required to test all cattle over 24 months of age for a period of two years for purposes of determining the prevalence of BSE in the Canadian herd. Not until the prevalence is scientifically determined should the United States consider relaxing its border restrictions on Canadian cattle and beef.

4. Canada's Feed Ban, Its Principle BSE defense, is Less Stringent than the United States' Feed Ban and the United States Should Not Accept Imports from Any Country that has Not Implemented Identical Feed Restrictions and that has Not Enforced Such Restrictions for at Least as Long as the United States.

It appears that Canada's feed ban implemented in 1997 exempts "rendered animal fat from all species" from its list of prohibited feeds.⁸ The United States' feed ban, however, does not include this exemption.⁹ In addition, Canada continues to allow the feeding of mammalian blood to ruminant animals.¹⁰ The United States is finalizing more stringent regulations to prohibit the feeding of mammalian blood and blood products to ruminants.¹¹ APHIS is silent on whether Canada has any plans to modify its feed ban so as to be in compliance with the United State's feed ban.

It further appears that Canada has only prohibited the practice of including beef derived from downer animals in export approved facilities.¹² APHIS is silent on whether Canada has any plans to adopt the additional restrictions proposed by the FDA to ban "any material from nonambulatory or dead cattle, as well as SRM and mechanically separated beef, from FDA-regulated human food, including dietary supplements and cosmetics."¹³

Under no circumstances should the United States accept any cattle, beef, or beef products from countries that do not maintain identical or more stringent safeguard measures than is presently required or presently proposed in the United States and which measures have been enforced for at least as long as the United States'.

5. The Designation of Canada as a Minimal Risk Region for BSE is in Direct Contradiction of the Scientifically Established and Internationally Accepted BSE

⁸ Canada: A Minimal BSE Risk Country, Canadian Food Inspection Agency, Animal Products, Animal Health and Production Division, October 2003.

⁹ 21 CFR 589.2000, Animal Proteins Prohibited in Ruminant Feed, at 541.

¹⁰ Canadian Food Inspection Agency's (CFIA) Feed Ban, Canadian Food Inspection Agency, Animal Products, Animal Health and Production Division, available at <http://www.inspection.gc.ca/english/anima/feebet/rumin/ruminfse.shtml>, downloaded March 10, 2004.

¹¹ Explanatory Note: Risk Analysis: BSE Risk of Importation of Designated Ruminants and Ruminant Products from Canada into the United States, USDA Animal Plant Health Inspection Service, Veterinary Serviced, February 2004, at 4.

¹² Id. at 8.

¹³ Id. at 5.

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Risk Classifications of the World Organization for Animal Health or Office International des Epizooties (OIE).

According to the OIE's BSE risk classification standards, Canada became ineligible for a "BSE provisionally free" classification upon the first discovery of BSE in a native Canadian cow on May 20, 2003. As a result of this case, Canada can achieve no higher than a "BSE moderate risk" classification because it does not meet the "BSE minimal risk" classification requirement that a country with a native case of BSE must have had its feed ban in place for 8 years before being upgraded to the "BSE minimum risk" classification. Thus, Canada will be recognized by the international community as no better than a "BSE moderate risk" country for approximately 1 ½ years because Canada's feed ban was not implemented until late 1997.

The APHIS proposal to designate Canada as a minimal risk region, therefore, is not based on any internationally accepted scientific standards and should be withdrawn.

6. By Unilaterally Designating Canada as a Minimal Risk Region in Direct Contradiction of the Internationally Accepted and Scientifically Established OIE Risk Categories, APHIS Will Cause Direct Economic Harm to the U.S. Cattle Industry.

The various BSE risk classifications established by the OIE are used by over 164 World Trade Organization (WTO) member countries to evaluate the relative BSE risks associated with importing ruminant and ruminant products from various countries. Many countries, including the United States, have elected not to assume the BSE risks associated with importing from countries that cannot meet the eligibility standards for an OIE BSE Free or BSE Provisionally Free classification. Common sense suggests that as a country's BSE risk increases, fewer countries will be willing to assume the greater risk of importing from that country if similar products are available from countries harboring a lesser BSE risk.

By unilaterally designating Canada as having less risk than that established by the OIE, countries that purchase U.S. exports will immediately recognize that the United States is importing products from a country with a higher BSE risk than they would be willing to assume. This very situation already occurred in 2003 when both Japan and South Korea threatened to discontinue importing United States beef unless the United States label all products destined for these countries with a label guaranteeing the product did not contain any beef derived from Canadian cattle. It is important to note that both Japan and South Korea, our first and third largest beef export customers, respectively, maintained this export restriction on and after APHIS's November 4, 2003, proposed rule. Therefore, it is clear that United States export markets will be adversely affected, should the United States attempt to reclassify Canada as having a more favorable risk designation than is recognized by the OIE.

As evidenced by the approximate 20 percent reduction in U.S. cattle prices following the export restrictions placed on the United States by approximately 90 percent of our beef export customers, actions that cause restrictions on U.S. beef exports translates to lost revenues for live cattle producers. APHIS should withdraw its proposed rules to prevent additional harm to U.S. producers.

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7. **A Prerequisite to Restoring Canadian Imports Must be to Restore Export Markets for the United State's Beef and Cattle Industries.**